DOCUMENT RESUME

ED 238 063 CS 504 482

AUTHOR Levesque, Cynthia
TITLE Drug Advertising and the FDA.
INSTITUTION Freedom of Information Center, Columbia, Mo.
REPORT NO FOI-484
PUB DATE Nov 83
NOTE 9p.
PUB TYPE Information Analyses (070)

EDRS PRICE MF01/PC01 Plus Postage.
DESCRIPTORS *Advertising; Business; *Business Responsibility; *Consumer Protection; Disclosure; *Drug Legislation; *Mass Media Effects; Medicine; *Merchandise Information; News Media; Organizational Communication; Propaganda
IDENTIFIERS Eli Lilly and Company; *Food and Drug Administration; Media Role; Oraflex; Prescription Drugs

ABSTRACT

With increases in consumer focused advertising for prescription drugs, the Federal Drug Administration has renewed efforts to protect the public from false advertising. In 1982, it charged that the press kits Eli Lilly and Company distributed to reporters on its new antiarthritis drug, Oraflex, misrepresented the product. It recommended that Lilly both remove its claim that the drug halted or reversed arthritis and add a list of possible serious side effects from the drug, such as liver damage. Lilly, however, failed to respond. When criticized by a House of Representatives subcommittee for its slowness in acting, the FDA responded that it was prevented by the First Amendment from taking serious action against Lilly until the press release was proven to be misleading the public. The FDA's clinical investigations office then recommended prosecuting Lilly for failing to report adverse reactions on four drugs, including Oraflex. Although withdrawing the drug from the market, the company continued to maintain that its press kit was accurate and balanced. The FDA is also having difficulty regulating the promotion of drugs awaiting FDA approval. Since preclearance of ads is not required, it is unclear how to remedy ads found to be misleading. The FDA continues, however, to study and to try to control direct-to-consumer drug advertiseme (MM)

**********
* Reproductions supplied by EDRS are the best that can be made *
* from the original document. *
**********

U.S. DEPARTMENT OF EDUCATION
NATIONAL INSTITUTE OF EDUCATION
EDUCATIONAL RESOURCES INFORMATION CENTER (ERIC)

X This document has been reproduced as received from the person or organization originating it.

☐ Minor changes have been made to improve reproduction quality.

• Points of view or opinions stated in this document do not necessarily represent official NIE position or policy.

ED238063

SCHOOL OF JOURNALISM, UNIVERSITY OF MISSOURI AT COLUMBIA
NOVEMBER, 1983

"PERMISSION TO REPRODUCE THIS MATERIAL HAS BEEN GRANTED BY

Freedom of Information Center

TO THE EDUCATIONAL RESOURCES INFORMATION CENTER (ERIC)."

# DRUG ADVERTISING AND THE FDA

## FREEDOM OF INFORMATION CENTER REPORT NO. 484

**This report was written by Cynthia Levesque, a master's candidate at the University of Missouri School of Journalism.**

In the past 20 years, the pharmaceutical industry has become one of the most competitive industries in the United States. This competition has spurred drug companies to aim beyond doctors — their traditional targets — to try to capture the attention of the American public.

Most large pharmaceutical firms have permanent public relations staffs to distribute press releases and kits to members of the press. The press, in turn, passes the word of the new drugs on to the public.

When they can't count on the media, companies do their own advertising in daily newspapers and consumer magazines. But along with capturing the attention of the public, the drug advertisements have caught the eye of the Federal Drug Administration.

After observing the promotion of drugs not yet approved and the distribution of press kits containing false and misleading claims, the FDA has reaffirmed its right to regulate this type of publicity.

The outcries of consumer groups prompted the agency to ask companies to hold off on all consumer drug ads until a policy could be agreed on. But one incident in particular, led the FDA to take a tough stand on prescription drug publicity to consumers. It involved the drug Oraflex.

### THE ORAFLEX CASE

On April 15, 1982, the FDA gave approval to Eli Lilly & Co. of Indianapolis to market the long awaited anti-arthritis drug Oraflex (benoxaprophen) in the United States. The drug had been available in Britain under the brand name of Opren for a year and a half.

Oraflex was introduced to the American public through one of the most intense publicity campaigns ever undertaken for a prescription drug. More than 150 newspapers and several hundred radio and television stations heralded the news that Oraflex could stop arthritis with minimal side effects. This claim was based on information in press kits distributed by the company — kits that the FDA had previously demanded Lilly change because they contained misleading information.

Oraflex made headlines again just 14 weeks later when it was taken off the market worldwide after the deaths of more than 70 of its users and reports of side effects in more than 4,000.

Here's the Oraflex story.

In March 1982, at a meeting between Lilly and FDA officials, the FDA demanded that Lilly change the thrust of its proposed publicity campaign for the drug. The FDA officials argued that there was no difference between Oraflex and other anti-arthritis drugs except for some side effects peculiar to Oraflex. Lilly had claimed that Oraflex was unique among drugs in its class.[1]

A few weeks later, the head of FDA's Division of Drug Advertising and Labeling, Peter Rheinstein, demanded that Lilly hold back the press kit because it contained the false claim that Oraflex "halted or reversed the underlying arthritis."[2]

Nevertheless, in mid-April, the FDA sent a letter to Lilly advising the company to change the press kit. The agency said the kit's suggestion that Oraflex halted or reversed arthritis was inappropriate.[3]

In early May, the **British Medical Journal** reported five cases of jaundice that resulted in death from renal failure in five elderly people taking benoxaprophen.

Lilly notified the FDA of the five deaths three days later. But on May 19, Lilly distributed almost 6,500 press kits at press conferences in New York, Chicago and Los Angeles. The kits contained much of the material Rheinstein objected

**Summary:**

With competition in the drug industry has come increased advertising and promotional activity. The dangers of false drug advertising to consumers has lead the Federal Drug Administration to attempt to regulate such advertising.

IR 304 482

to and made no mention of liver damage as a possible side effect.

Two days after distribution of the press kits, the FDA wrote Lilly an informal letter saying that the claims made in the press kits appeared to be lawful, but that they were unethical. The agency noted that the kit "minimized the drug's potential for adverse reactions," and that "the materials went far beyond the approved labeling for the product into the realm of theoretical benefit . . . of unproven clinical significance."[4]

**Commercial Success Amid Controversy**

Questionable claims notwithstanding, Oraflex immediately became a hot news item. ABC news called the drug a "breakthrough in the treatment of arthritis." The **National Enquirer** ran a front page headline reading "Arthritis — Sensational New Drug." **Time** magazine repeated Lilly's claim that "Oraflex may actually slow the progression of the disease."

Side effects, according to the articles, were "minimal." The **Time** story reported that Oraflex caused 50 percent fewer gastrointestinal side effects than aspirin. The article also said the drug caused sun sensitivity leading to an itchy rash in about 20 percent of patients, but that the reaction could be avoided by using a sunscreen or developing a suntan before using the drug. The **National Examiner** said that "in a mere one percent of cases (it caused) a mild discoloration in skin and nails when exposed to sunlight."

These claims were taken directly from the press kit.

The result of all the favorable publicity was a $1 million a week jump in sales of Oraflex — from 2,000 to 55,000 prescriptions a week.

In mid-June, a 47-year-old woman from Las Vegas became the first American to die from liver failure while taking Oraflex. She had been taking the drug for less than a month.

The FDA Arthritis Advisory Committee responded immediately with a recommendation that labels be attached to Oraflex and ten similar drugs warning of possible liver damage.

Ralph Nadar's Health Research Group, a consumer protection organization, called on Health and Human Services Secretary Richard Schweiker to ban Oraflex. In a letter to Schweiker, Dr. Sidney Wolfe, director of the group, cited the deaths of 12 elderly women in Great Britain who had been taking Oraflex. All the deaths were characterized by liver injury and terminal kidney failure. An FDA review linked seven of the deaths to the drug.

At a meeting in late June, Lilly and FDA officials discussed several reported cases of renal and liver toxicity in Britain, Denmark and the United States among Oraflex users. The FDA recommended that the labeling be changed to include a warning of liver toxicity and to recommend a lower dosage for elderly users.

Also discussed were several cases of gastrointestinal bleeding and peptic ulcers that were linked to 13 deaths in Britain, which had announced plans to change Oraflex labeling to contraindicate the drug for people with peptic ulcers.

In July, Lilly created an Oraflex hotline and gave members of the broadcast media a number to call for a recorded message about the drug that could be played on the stations. The message included the statement, "Oraflex . . may also limit the actual joint destruction in humans caused by the progression of the disease."[5] There was no mention of side effects in the message.

**The FDA Presses its Case**

With the issue of the press kits still unresolved in late July, Jerome Halperin, a consumer safety officer from the Division of Advertising and Labeling, wrote to Lilly requesting that the company distribute a press release correcting the misleading statements of the original kit.

He wrote that the wording of the release would have to be approved by the FDA and given to all recipients of the May 19 press kit. Halperin warned that if Lilly did not comply the FDA was prepared to take legal action.

The Federal Food, Drug and Cosmetic Act provides for injunction and/or seizure of misbranded products. The FDA charged Lilly with violating the act by exceeding the FDA-approved labeling in the claims of efficacy and safety. Lilly exceeded the efficacy claims by suggesting that Oraflex could remit or cure arthritis and the safety claims by minimizing the adverse reactions.[6]

Referring to the March 29 meeting at which the FDA demanded Lilly change the focus of its campaign, Halperin wrote,

> Notable differences between this drug and other class members are theoretical and highly speculative. While the Lilly personnel were advised that in vitro and/or animal findings may be discussed, it was clearly stated that no clinical claims could be based upon such findings.
>
> This point was repeated several times during the many discussions which took place between Lilly representative and the FDA in the development of acceptable promotional materials.[7]

Halperin was referring to the following paragraph from the original Oraflex press kit:

"In animal studies, benoxaprophen has been shown to suppress bone damage and arrest the development of arthritis. Preliminary evidence also suggests that the disease process may be retarded in human patients given Oraflex."[8]

Halperin then discussed eight aspects of the press kit that were considered misleading, including the statement of photo reactions, which included "either of two **mild**, transient, and avoidable side effects found during exposure to sunlight in **some** arthritic patients taking Oraflex . . . (and) a **slight** lifting of the outer ends of one or more fingernails from the fingertips."[9]

Halperin noted that the approved labeling describes the photo reaction as "sharp burning or itching," and the lifting of the nails involving up to one-half or more of the nail plate and possibly including the toenails. This reaction was seen in up to two-thirds of the patients studied.

**Congressional Response**

Congress got involved in the controversy in early August when the House Intergovernmental Relations and Human Resources Subcommittee began a two-day hearing on the new drug review process. The hearing, which was chaired by Rep. L.H. Fountain, was held to evaluate the FDA's new drug approval procedures.

The hearing revealed that three cases of jaundice had occurred in patients taking Oraflex in the United States early in 1982 and had slipped by the FDA in the approval process. FDA officials discovered the cases in unprocessed data of the Investigational New Drug (IND) application. The search began only after the June 23 meeting between Lilly and the FDA, during which liver problems were discussed. A fourth case of jaundice that had occured before approval had gone into the New Drug Application (NDA).[10] All four cases should have gone into the NDA.

Regulation of promotional practices of drug companies was also discussed at the hearing. Rep. Fountain asked Peter Rheinstein of the FDA's Division of Drug Advertising and Labeling why the agency took two months to act against the Oraflex campaign. Rheinstein answered that the real test of whether something is misleading is whether someone has actually been misled. That is why, he said, the FDA initially called the claims "unethical." Only after the public had been misled by news reports did the agency accuse Lilly of violating the Federal Food, Drug and Cosmetic Act. When Rheinstein was again challenged on the FDA's delay in acting against the violations, FDA commissioner Arthur Hayes responded:

"If you want us to discuss this on your presumption that any press release by a drug firm that mentions any of their products is automatically under out regulatory purview, then we have a big discussion about law, first amendment, and I do not know what else."[11]

Hayes was then asked to submit to the subcommittee a statement of the FDA's interpretation of its legal authority over press kits.

The statement said that the FDA considered the kits labeling and that it had the authority to regulate them even though they were not listed in the Act. The agency also said that it is unnecessary to prove that someone has been misled; showing that an item may mislead is enough to prove a violation.

**The FDA Takes Action**

On Aug. 4, 1982, the FDA clinical investigations office recommended criminal prosecution of Lilly for failing to report adverse reactions in four drugs, including Oraflex.

James Campbell, a former Lilly employee, told the FDA that many side effects of Oraflex that were cited in Lilly's initial application to test the drug did not appear in the application to market Oraflex. Physicians testing the drug reported 173 side effects, including gastrointestinal problems, photo sensitivity and loosening fingernails, that Lilly did not inform the FDA of.[12]

The day after the FDA recommended criminal prosecution of Lilly, the company voluntarily withdrew Oraflex from the market. More than 11 people in the United State had died while taking the drug.

Almost three weeks later, Lilly responded to Halperin's letter of late July. In the response, John Holt, secretary and general counsel for Lilly, held that the press kit was accurate and balanced and that the media's claims varied from the material provided.

The company defended its position by noting that each press kit included a package insert containing FDA-approved statements of indications, contraindications, warnings and side effects.[13]

Furthermore, Lilly argued that the Oraflex press kit was not "labeling" within the definition of the Federal Food.

## A Brief History of the Regulation of Drug Advertising

Before October 10, 1962, the Federal Trade Commission was responsible for regulating advertising of all domestic commodities in interstate commerce. But the Wheeler-Lea Act, passed by Congress in 1938, exempted advertisements directed to health professional from FTC control. Congress believed that physicians were able to judge whether an ad was misleading and, hence, did not need the same protection given the public.

In 1960-61, Sen. Estes Kefauver's Subcommittee on Antitrust and Monopoly found that advertising to the medical profession had resulted in serious abuses. Kefauver's work led to the Drug Amendments of 1962 (sometimes called the Kefauver-Harris Amendments).

Essentially, the amendments require that prescription drug advertisements include the identity of the drug and its quantitative composition and a brief summary of effectiveness, side effects and contraindications. The FDA was given responsibility for enforcement and jurisdiction over intrastate distribution was included.

In 1967, the FDA added to the regulations the requirement that ads be balanced physically and contextually.

Three years later the agency established The Division of Drug Advertising and Labeling to regulate prescription drug advertising and labeling. The department is headed by Peter Rheinstein and staffed by five consumer safety officers, a technician, a staff fellow and two secretaries.

The division encourages new drug sponsors to submit their promotional material for review prior to release. Although many firms submit their material for opinion, advertising and promotional materials are not subject to preclearance.

The division also requires companies to submit a package insert for review prior to a new drug's approval. This insert is called the "approved labeling."

Package labeling must contain indications, effects, dosages, methods of administration, warnings, side effects and contraindications. Parts of the package labeling must be written in the same language and with the same emphasis as the approved labeling, and it must be consistent with the approved labeling.

The Federal Food, Drug and Cosmetic Act defines labeling as ". . . all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The act contains a list of types of labeling that fall under the act and, hence, are subject to legal sanctions if they contain information that is false, misleading or lacking fair balance. The list includes brochures, booklets, mailing pieces, bulletings and other types of printed, audio and visual materials. It does not include press kits.

Drug and Cosmetic Act because it was not intended for use by members of the medical profession.The FDA disagreed with Lilly's contention that the press kit was not labeling. In a letter written to the company on Nov. 19, Halperin argued that while the list of labeling examples in the act was comprehensive, it was not exhaustive.

The FDA also disagreed with Lilly's claim that the kit was not intended for distribution to health care professionals.

> Although we do not interpret 21 CFR 202.1(1)(2) (of the act) as requiring such an intended audience, the impact of the materials reached that audience. Distribution of material to the medical press, particularly the extensive distribution that occured here, cannot but suggest an intent that the material be disseminated specifically to the health professionals.[14]

A month earlier, in a speech before the Pharmaceutical Manufacturers Association, Kenneth Feather of the FDA had clarified the agency's position on press kits.

"When 'press' and 'regulation' are mentioned in the same breath," he said, "you are besieged by constitutional lawyers explaining the First Amendment to you."[15]

He assured the group that the FDA had no intention of getting into preclearance of press kits. He did point out, however, that recent decisions by the Supreme Court have established the right to regulate commercial speech to make sure it is truthful and not misleading.

## PREAPPROVAL PROMOTION

To gain a competitive edge, more firms are publicizing the benefits of products that are still under investigation. Such preapproval publicity has become increasingly common in the past two years, especially when two companies are about to market an identical or similar product, when a new class of drugs will be introduced, or when two or more companies are working on the same new indication for an existing drug.

The Food, Drug and Cosmetic Act restricts a sponsor's promoting safety or efficacy claims of a drug that's under investigation to establish the validity of such claims.

The guidelines on preapproval promotion, adopted by the Division of Drug Advertising in May 1982, permit the naming only of a broad category of therapy, not a specific drug. A company may also announce the name of an investigational product without mention of safety or effectiveness. A company may not use both options.

The law against preapproval promotion, however, is difficult if not impossible to enforce. Although the FDA occasionally sends letters to companies requesting that preapproval campaigns be stopped, the agency has never resorted to revoking a new drug's application as punishment.

An artical in the **Washington Post** on Nov. 12, 1982, said the FDA was compiling a "black list" of companies conducting preapproval campaigns. The domestic companies listed were Marck, Marion, Pfizer, Schering and Syntex.[16]

Charles Rouse, manager of public affairs for Marion Laboratories in Kansas City said he was unaware of the "black list," and he readily explained Marion's preapproval publicity tactics. Marion issues grants to physicians to test drugs prior to approval. The company then puts editors in touch with doctors they know will speak favorably of the product. Sometimes Marion sends preapproval press kits to these doctors to prepare them for their discussion with the editor.

"We'll do everything we possibly can," Rouse said when asked about the ethics of preapproval publicity. "We're in the business to make money."

The section of the Food, Drug and Cosmetic Act regulating preapproval promotion begins, "Neither the sponsor nor any person acting for or on behalf of the sponsor shall" be involved in preapproval promotional activities.

Drug companies being thus restricted, doctors are useful because they appear to be independent from the company.

"It's hard to prove that it is occuring," said Bill Purvis, of the Division of Drug Advertising and Labeling, about Marion's tactics. "I suspect it and so does everybody here. It gets cloudy around the First Amendment rights. An investigation would involve a great amount of time." Purvis also pointed out that there is a fine line between acceptable dissemination of information on an investigational drug and unacceptable promotion.

## DIRECT-TO-CONSUMER ADVERTISING

Merck Sharp & Dohm pharmaceutical broke new ground by being the first to advertise a prescription drug to consumers. The company's ad for Pheumovax, a pneumonia vaccine, appeared in **Reader's Digest, Modern Maturity** and eight regional newspapers in the fall and early winter of 1981.

Since then, however, only two other prescription drugs have been advertisined to consumers, both with unfavorable results.

The first, a direct-to-consumer promotion of a rebate on an antiarthritis drug called Rufen, was widely cirticized by medical professionals. Doctors said the rebate would encourage patients to pressure their doctors to change their prescriptions to Rufen, though Rufen may be a poor choice for therapy for them.

The second, an ad for Zovirax, an ointment used to threat genital herpes, contained two parts that violated the Federal Food, Drug and Cosmetic Act. The ad stated that Zovirax was approved by the FDA and suggested that the drug was useful in treating recurrent herpes. Such claims are outside of approved labeling guidelines.

The full-page ad appeared in the **Washington Post** in May 1982. It was placed by Peoples Drug Store.

According to a memo written by Arthur Yellin of the Division of Drug Advertising and Labeling, Leonard DeMino, director of professional relations for Peoples, checked with the FDA's consumer inquiry branch before placing the ad. Harold Davis, who handles general questions for that branch, put DeMino on hold while he asked Bill Purvis of Yellin's department about the rules of direct-to-consumer ads. Thinking that Davis was seeking information for a consumer, Purvis gave an incomplete answer that was relayed to DeMino. DeMino was advised to check with Yellin's department before planning any more consumer ads, but not requested to remedy the ad.[17]

Last November, CIBA pharmaceutical company voluntarily submitted an ad for Transderm-Nitro, a nitroglycerin product, to the FDA for review. The ad was scheduled to ap-

pear for six consecutive weeks in the **Chicago Tribune**, the **Houston Post** and the **Cleveland Plain-Dealer**.

The FDA vetoed the ad because the drug had been given only conditional marketing approval pending completion of review of data on effectiveness.

CIBA is now planning an advertising campaign for Transderm-Scope, which is used to prevent motion sickness.

But the company is one of only a few pharmaceutical companies planning direct-to-consumer advertising. The FDA has asked the industry to hold off on consumer advertising for a while. There are many unanswered questions about the effects of this type of advertising. To answer some of these questions, the FDA began a series of meetings between consumers and representatives of the pharmaceutical and advertising industries and the medical profession. The feedback from the meetings may also help the FDA decide if and how a separate policy should be implemented for direct-to-consumer advertising. Now advertisers must follow the same rules that apply to advertising directed to medical professionals.

The first of these meetings was held on March 28, 1983, in Washington. Some groups opposed the advertising while other questioned the advisability of promoting prescription drugs to consumers. No group, including the drug companies, expressed firm support.

The Consumer Federation of America opposed the advertising for several reasons. Anne Averyt, Food and Drug specialist for the federation, said that the ads would be misleading because they would downplay side effects and contraindications, would raise the cost of drugsand lead to abuse.

"Perhaps our greatest concern with such individual drug ads is the temptation for abuse . . . to market Valium as the solution to the housewife's blues as it was in the medical journals only a few years ago," she said.[18] The American Association of Retired Persons opposed direct-to-consumer advertising for the same reasons.

The attitude of the pharmaceutical industry is evident in the results of a 1982 survey that the American Pharmaceutical Association presented at the meeting. Sixty-nine percent of the pharmacists surveyed objected to direct-to-consumer advertising, 62 percent believed advertising would increase the cost of drugs and 53 percent believed advertising would increase prescribing.

A representative for the American Medical Association said that the advertising should contain a balance of information on the benefits and risks of drugs, and that it may be more appropriate for drugs used to prevent, rather than treat, disease.

Only one organization, the American Association of Advertising Agencies, suggested a policy. AAAA Executive Vice President Charles Adams said that direct-to-consumer advertising containing the required "brief summary" would scare patients unfamiliar with the language used to describe side effects. As an alternative to the brief summary, Adams proposed a "layman's code," which would read,

> This pharmaceutical product can only be prescribed by a registered physician. Almost all medicines have side effects and limits of use, and only a physician knowledgeable of your particular case can determine the correctness of your use of this product. Follow his advice and his counsel, and be careful to take any medicine he prescribes only as his instructions indicate.[19]

One of the most serious questions related to direct-to-consumer advertising is how to remedy ads found to be false or misleading. Since preclearance of ads is not required, occasional misleading statements are certain to occur. The most common remedy taken by the FDA has been to tell the company to stop the campaign by issuing a notice of violation. In 1979, notices of violation resulted in cancelation of 185 pieces of advertising. In cases where the violations are serious, the FDA may require the firm to send out "Dear Doctor" letters informing physicians of the violation in the ad.

A more common solution is the remedial ad. A remedial ad is one which contains a boxed statement that the ad is replacing one found to be misleading by the FDA. It must contain a "carry-over" element of the original ad such as the background or photograph of the original ad to aid reader recall. The remedial ad must be run twice in the same publication in which it was first run.

The FDA also has the right to seize a product for advertising violations. This route is rarely taken, however, if there is no problem with the product.

Bill Purvis of the Division of Drug Advertising said he thinks remedial ads would be used in cases of violation in direct-to-consumer ads. The problem with this remedy is that unlike physicians who receive medical journals by subscription, many consumers buy one issue of a magazine and not the next. Purvis does not see this as a problem. If a direct-to-consumer ad had to be remedied, he said, the press "would have a field day. It would go out on all the wires."

**Author's note:**

Much credit for this report goes to Bill Purvis of the FDA's Division of Drug Advertising and Labeling for quickly responding to my Freedom of Information request by sending the Oraflex letters, the Peoples Drug Store telephone call memos and for general information about advertising regulation.

If the proposed Hatch bill, S.B. 774 had been in effect, I would probably still be waiting for the material today. The bill, proposed by Sen. Orrin Hatch, R-Utah, would require the FDA to notify a firm before releasing information submitted by the firm to the agency.

Under the Hatch bill, the FDA would notify a company that a request for its data had been made no later than 10 working days after receiving the request. The company would then have 10 working days in which to file objections to release of the date. If the agency decided to release the data over the company's objections, it would have to wait 10 more days, during which time the company could seek an injunction to prevent release. The bill also provides that an agency may require a submitting firm to designate material it considers proprietary and thus exempt from release under the FOI Act. Material not so designated could be released by the FDA without notifying the company.

When asked about the effect of the bill on the agency's FOI department, Purvis said, "It would set us back 2,000 years."

FOOTNOTES

1. Jerome Halperin to Richard D. Wood, U.S. Government File No. HFD-173-1-2, Washington, D.C., July 27, 1982.
2. "Eli Lilly Accused in FDA Documents of Not Reporting Adverse Drug Reactions," **Wall Street Journal**, Aug. 4, 1982.
3. Paul Jacobs, "FDA Adopting Tougher Stand on Drug Advertising," **Los Angeles Times**, Dec. 30, 1982, P. 1ff.
4. Judith Randal and William Hines, "A Patent Hustle," **The Progressive**, November 1982, pp. 37-40.
5. Subcommittee of the Committee on Government Operations House of Representatives, "The Regulation of New Drugs by the Food and Administration Printing Office, 1982, p. 485.
6. Halperin to Wood
7. Ibid.
8. Subcommittee, p. 486.
9. Halperin to Wood, p. 3.
10. Subcommittee, p. 117.
11. Ibid., p. 505.
12. Ibid., p. 161.
13. John Holt to Arthur Yellin, U.S. Government File No. HFD-173-1-2, Washington, D.C., Aug. 2, 1982.
14. Jerome Halperin to Jojm Holt, U.S. Government File No. HFD-173-1-2, Washington, D.C., Nov. 19, 1982.
15. Kenneth Feather, Transcript of Speech for the Pharmaceutical Manufacturing Association Public Affairs Section Meeting, Washington, D.C., Sept. 15, 1982.
16. Morton Mintz, "Heart Drug Ads Delayed by Warning," **The Washington Post**, Nov. 12, 1982, p. B5.
17. Arthur Yellin, Telephone conversation with Leonard DeMino, Nov. 19, 1982.
18. Executive Summary of the National Consumer Exchange Meeting, March 28, 1983, p. 2.
19. "Layman's Code for Side Effects Information in Direct to Consumer Ads Could be Alternative to 'Bried Summaries,' " American Association of Advertising Agencies Suggests," F-D-C Reports, April 4, 1983, p. 5.

Below is a list of the most recent **Freedom of Information Reports** available for purchase. A complete listing will be mailed upon request.

392. **Access to FDA Information,** (Sinovic) July 1978
393. **FOIA: What's A Trade Secret?** (Hawker) July 1978
394. **Access to Medical Records,** (Cooper) August 1978
395. **The Reporter's Control of News,** (Powell) Sept. 1978
0019 **A Look at Journalism Reviews,** (Bertrand) Sept. 1978
396. **The Camera Comes to Court,** (Floren) Oct. 1978
397. **Public Records and Public Meetings,** (Kelly) Dec. 1978
398. **The Children's Advertising Battle,** (MacKie) Jan. 1979
399. **CATV and the Broadcasters,** (Flanagan) Jan. 1979
400. **Eyeing New York's Newspaper Strike,** (Fishleder) Feb. 1979
401. **Parents Protest Textbooks,** (Hung) March 1979
402. **Press Councils in Canada,** (Reddic) March 1979
403. **The Supreme Court's Search Ruling,** (Kelly), April 1979
404. **Conneticut's FOI Commission,** (Gentry) May 1979
405. **Press Access to Jails and Prisons,** (McCormick) June 1979
406. **Access to NRC Records,** (Kalin) July 1979
407. **A Guide to the EDA,** (Miller) July 1979
408. **Public Files of the SEC,** (Woodward) Aug. 1979
409. **The FTC: A Fount of Business Data,** (Bryant) Sept. 1979
410. **The FCC: A Research Tool,** (Wilson) Sept. 1979
411. **Access to Federal Officials' Papers,** (Schwaller) Oct. 1979
412. **Access to Personal Medical Records,** (Weisenstein) Nov. 1979
413. **Physician Advertising: The Debate,** (Bruhn) Nov. 1979
414. **National Archives and its Archivist,** (Caprino) Dec. 1979
415. **The FCC and the Electric Church** (Abrams) Jan. 1980
416. **Religious Groups v. TV's Sex, Violence,** (Schicht) Jan. 1980
417. **Who Runs Presidential Campaigns? (Kindsvatter) March 1980**
418. **Press Relations: Carter's Example,** Kindsvatter) March 1980
419. **Pressure Groups v. the Movies,** (Froelich) April 1980
420. **Foreign Controls on U.S. Media,** (Ramos) May 1980
421. **The Non-Aligned News Agency Pool,** (Sebaei) May 1980
422. **Florida's Bold Experiment,** (White) June 1980
423. **Free Press-Trial Confusion,** Newman) July 1980
424. **Speaking Freely on Military Bases,** (Kindsvatter) July 1980
425. **Publishing Juvenile Names,** (Hubbard) Aug. 1980
426. **Official Secrecy: Rising or Demising?** (Appleton) Sept. 1980
427. **The American Press Ombudsman,** (Mogavero) Sept. 1980
428. **Access to Congressional Records,** (Relyea) Oct. 1980
429. **Secrecy in Science,** (Bushman, Porter) Nov. 1980
430. **The CIA and Censorship,** (Ruffenach) Nov. 1980
431. **Reporters' Committee for Freedom of the Press,** (Gerstein) Dec. 1980
432. **The CIA-Media Connection,** (Sanderson) Jan. 1981
433. **Soviet Disinformation,** (Cavenagh) Jan. 1981
434. **Litigation Costs and Self Censorship, (Picard) Feb. 1981**
435. **Minority Broadcasting Ownership, (Taylor)**
436. **Minorities in the Media,** (Sherard, Lynch, Heard) Mar. 1981
437. **FoI and Fire at the MGM Grand,** (Thompson) April 1981
438. **Canada's Access Legislation,** (O'Reilly) May 1981
439. **Access To Computerized Records,** (Pfeffer) May 1981
440. **Reporter Licensing,** (Henderson) June 1981
441. **An Adoptee's Right to Know,** (Abernathy) July 1981
442. **Cryptology and National Security,** (Peterson) July 1981
443. **Censorship in Public Schools,** (Sneller) Aug. 1981
444. **Voluntary Press-Bar Agreements,** (Kirby) Sept. 1981
445. **Missouri Public Service Commission,** (Sickendick) Sept. 1981
446. **Prior Restraint and the Progressive,** (Wrenden) Oct. 1981
447. **New Zealand's Proposed FoI Law,** (Chetwynd) Nov. 1981
448. **Discipline of Foreign Correspondents,** (Picard) Nov. 1981
449. **Fair Information Practices Laws,** (Kilbourne) Dec. 1981
450. **Proposed FOIA Amendments-1,** (Perlmutter) Jan. 1982
451, **Proposed FOIA Amendments-2,** (Perlmutter) Jan. 1981
452. **Christians, Consumers and TV,** (Gliatto) Feb. 1981
453, **The Plight of the Public Libraries,** (Rose) March 1981
454, **Watchdogging the IRS,** (Engardio) March 1982
455. **Intelligence Identities Protection,** (Sanderson) April 1982
456. **Newspaper Preservation Act Update,** (Keep) May 1982
457. **Use of the FOIA,** (Archibald) May 1982
458. **Attorneys and Advertising,** (Brown) June 1982
459. **FCC and the Sunshine Act,** (Weiss) July 1982
460. **High School Press Pressures,** (Rogers) July 1982
461. **The Prison Press,** (Hausman) Aug. 1982
462. **The Australian Freedom of Information Act,** (Chetwynd) Sept. 1982
463. **Business and the Media,** (Barchie) Sept. 1982
464. **Reporter's Privilege,** (Slasman) Oct. 1982
465, **Columbia Daily Tribune v. The Curators of the University of Missouri: A Case Study,** (Watt) Nov. 1982
466. **Functional Illiteracy,** (Hovey) Nov. 1982
467. **The Department of Education: A Reporter's Guide,** (Shannon), December 1982.
468. **Declassified Documents,** (Brown) January 1983.
469. **Government Classification: An Overview,** (Brown) January 1983.
470. **Voluntary Becomes Standard?: Bar-Press Codes After 'Swedberg',** (Kates) February 1983.
471. **Rich News: Metropolitan Dailies and the Urban Poor,** (Draper) March 1983.
472. **Demographics and the Dailies: Stalking the Upscale Reader,** (Hausman) March 1983.
473. **Five Years of Right of Publicity: The Aftermath of 'Zacchini v. Scripps-Howard',** (List) April 1983.
474. **The Federal Advisory Committee Act After Ten Years,** (Keep) May 1983.
475. **Naming the Rape Victim,** (Clay) May 1983.
476. **Exemption 6: Privacy Under The Freedom of Information Act,** (Abbott) June 1983.
477. **Exemption 4: Trade Secrets Under the Freedom of Information Act,** (Selby) July 1983

478. **Pentagon After Action Reports: The Jack Taylor Debate,** (Abbott) July 1983
479. **The Ombudsman and the News Media,** (Hudgens) August 1983
480. **Censorship in Schools: A Missouri Community's Experience,** (Edwards) September 1983
481. **Transborder Flow of Computerized Information: Controls and Restrictions,** (Schrader) September 1983
482. **Reagan Information Policy Shuts Up Government Critics,** (Christopher) October 1983

Additional copies of this report, and other Freedom of Information Center reports, may be obtained by writing the Center at Box 858, Columbia, Missouri 65205. There is a $1 charge for each single copy, 90 cents each for 25 or more copies, $60 per 100 copies, and $50 per 100 on orders of 300 or more copies.